Amendments to the Claims

The following listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-10. (Canceled)

11. (Currently amended) A method for making irbesartan comprising the steps of:

a) combining 2-butyl-1,3-diaza-spiro[4.4]non-1-ene-4-one and 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole in the presence of a phase transfer catalyst in a reaction system comprising organic and aqueous phases;

b) maintaining ~~heating~~ the combination at ~~to~~ a temperature of about 20° C ~~and~~ to about 95° C for a period of time sufficient to obtain 2-butyl-3-[2'-(triphenylmethyltetrazol-5-yl)-biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one;

c) separating the organic and aqueous phases;

d) removing solvent from the organic phase to obtain a residue of 2-butyl-3-[2'-(triphenylmethyltetrazol-5-yl)-biphenyl-4-yl methyl]-1,3-diazaspiro[4.4]non-1-ene-4-one;

e) dissolving the residue in a water-miscible solvent in the presence of a mineral acid to form a solution; and

f) basifying the solution with an inorganic base to obtain irbesartan;

~~g) removing the water-miscible solvent from the solution to obtain a precipitate of trityl alcohol;~~

~~h) separating the precipitated trityl alcohol from the solution; and~~

~~i) recovering irbesartan from the solution~~.

12. (Original) The method of claim 11 wherein the water miscible solvent is acetone.

13. (Previously presented) The method of claim 11 wherein the solution is basified to a pH of about 8 to about 12.

14. (Previously presented) The method of claim 13 wherein the solution is basified to a pH of about 9 to about 10.5.

15. (Previously presented) In a method of making irbesartan, the step of combining, in the presence of a phase transfer catalyst, a solution of 5-(4'-bromomethylbiphenyl-2-yl)-1-trityl-1H-tetrazole in a first solvent that is an aromatic or aliphatic hydrocarbon and a solution of 2-butyl-1,3-diazaspiro[4.4]non-1-ene-4-one in a second solvent comprising water and an inorganic base, whereby organic and aqueous phases are formed.

16. (Previously presented) The method of claim 15 wherein the first solvent is the aromatic hydrocarbon toluene.

17. (Original) The method of claim 15 wherein the phase transfer catalyst is tetrabutylammonium hydrogensulfate.

18. (Original) The method of claim 15 wherein the inorganic base is KOH.

19. (Previously presented) The method of claim 11, wherein the phase transfer catalyst is a quaternary ammonium compound or a phosphonium compound.

20. (Previously presented) The method of claim 11, wherein the phase transfer catalyst is tetrabutylammonium hydrogensulfate.

21. (New) The method of claim 11, wherein the organic phase comprises an aromatic or aliphatic hydrocarbon and the aqueous phase comprises water.

22. (New) The method of claim 21, wherein the aromatic hydrocarbon is benzene, toluene, m-xylene, o-xylene, or a tetralin.

23. (New) The method of claim 21, wherein the aqueous phase further comprises an inorganic base.

24. (New) The method of claim 24, wherein the inorganic base is potassium hydroxide, sodium hydroxide, or lithium hydroxide.

25. (New) The method of claim 11, wherein the maintaining step comprises heating the combination to a temperature of about 20° C to about 95° C.

26. (New) The method of claim 26, wherein the combination is heated to a temperature of about 90° C.

27. (New) The method of claim 11, further comprising recovering the irbesartan from the solution.

28. (New) The method of claim 27, wherein the recovering step comprises removing trityl alcohol from the solution.

29. (New) The method of claim 27, wherein the recovering step comprises removing the water-miscible solvent from the solution to obtain a precipitate of trityl alcohol, separating the precipitated trityl alcohol from the solution, and precipitating irbesartan from the solution.

30. (New) The method of claim 29, wherein the irbesartan is precipitated from the solution by acidifying the solution.